## REMARKS

Claims 13-16 are pending in the application. Claim 16 has been amended.

### Status of the Claims

Claim 16 has been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 13-16 have been rejected under 35 U.S.C. 103(a) as being unpatentable (i) over Rise et al. (5,752,930) in view of Urry (5,519,004), and (ii) over Heil, Jr. (5,041,107) in view of Urry. Applicants traverse the rejections and submit that the claims are patentable.

### Discussion

Claim 16 has been amended to remove reference to both poly(glycine-valine-glycine-valine-proline), and polylacticglycolic acid microspheres including dexamethasone. Support for this amendment is present in the application at paragraphs [0050] through [0052]. Entry of this amendment is appropriate and is respectfully requested.

### The Rejection of Claim 16 under 35 U.S.C. 112, First Paragraph

Applicants have deleted the reference to "polylacticglycolic acid microspheres including dexamethasone" from claim 16. Accordingly, the rejection of this claim under 35 U.S.C. 112, first paragraph has been rendered moot.

### The Rejection of Claims 13-16 under 35 U.S.C. 103(a) over Rise in view of Urry

Rise (the primary reference) discloses a device that infuses equal volumes of an agent to spaced sites in a patient. The device is particularly effective in administering low volumes of the agent to each of the spaced sites. As stated by Rise in the Abstract, the device (a catheter) has a plurality of fluid exits that are responsive to a first range of pressure on a fluid agent for delivering substantially the same flow rate of the agent through each of the exits into spaced infusion sites and responsive to a second range of pressure less than a threshold pressure on the agent for inhibiting the flow of the agent from any of the exits into any of the sites.

Rise further explains the operation of his device at column 1, lines 50-64 where he state that pressure is applied to the agent in the catheter at two different pressures, a first pressure and a second pressure, in the catheter. The first pressure is greater than the second

pressure. The first pressure, the threshold pressure" is sufficiently large to move the fluid along the catheter to contact all of the exits and overcome the fluid resistance that prevents the flow of fluid out of the openings. When the pressure is less than the threshold pressure, the flow of the fluid from the exits is inhibited or stopped.

Rise is silent with respect to the use of a drug delivery path preservation means that comprises a coating.

Urry discloses a bioelastomer that is compatible with and similar to the soft tissue at wound sites and which is biodegradable, if at all, to non-toxic components. The bioelastomer is said to be useful in facilitating healing by isolating the tissue at the wound from other tissue or surfaces thereby reducing the formation of unwanted adhesions to the other tissue or surface.

The Examiner urges that even though Rise fails to disclose the use of a drug delivery path preservation means that comprises a coating, it would be obvious to one of ordinary skill in the art to modify the device of Rise with the bioelastomer of Urry "for the purpose of low propensity of adhesion of proteins, cells, and other biological components that can result in impaired functioning." Applicants traverse this rejection and submit that the combination of these two references is inappropriate.

As shown above, Rise uses upon a sufficiently high pressure (the threshold pressure) to overcome any resistance to the flow of fluid out of the openings of the catheter and thereby dispense the fluid through the openings. When the appropriate amount of the fluid has been delivered, the pressure on the fluid is reduced below the threshold pressure and the fluid flow through the openings stops. Consequently, Rise teaches a device in which pressure is used to overcome resistance to the flow caused by any occlusion. As a result, the use of a coating such as suggested by the Examiner would not be suggested by Rise as there would be no reason to add such a coating to a device that already teaches how to overcome the problem that the Examiner argues is the reason to combine the references. Stated another way, the combination would solve a problem that Rise teaches does not exist.

Even if Rise and Urry were to be combined, the combination would not render the present invention unpatentable under 35 U.S.C. 103(a). Each of the present claims requires that the drug delivery system have a plurality of drug delivery ports that are movable between an open position to deliver the drug to the patient and a closed position. Nothing in either of Rise or Urry teach or suggest this feature of the present claims. In fact, since Rise relies upon the use of a pressure above a threshold pressure to deliver fluid through the openings and a

pressure below the threshold pressure to stop delivery of the fluid, the presence of ports that open and close would unnecessary and therefore not obvious to one of skill in the art.

Finally, it is noted that claim 16 has been amended to limit the coating to a material selected from the group consisting of connective tissue growth blocker, C-Proteinase blocker, and prolyl hydroxylase blocker. These materials are neither taught nor suggested by either Rise or Urry. Accordingly, claim 16 is patentable under 35 U.S.C. 103(a) over the combination of Rise and Urry for this additional reason.

**The Rejection of Claims 13-16 under 35 U.S.C. 103(a) over Heil in view of Urry**

Heil teaches the use of a plastic film that is attached to a catheter at two discrete points. The plastic film **covers** the ports. Rather than interacting with clot-forming substances, this plastic film provides a physical barrier that prevents the build-up of clots in the ports by preventing clot-forming substances from ever contacting the ports. Thus, Heil not only teaches a different structure and mechanism than is required by the present claims, it teaches that modifications to its structure are unnecessary. Consequently, it there would be no motivation to combine Heil with Urry to overcome a problem that Heil has already overcome. Stated another way, the combination would overcome a problem that Heil teaches does not exist.

Even if Heil and Urry were to be combined, the combination would not render the present invention unpatentable under 35 U.S.C. 103(a). As previously discussed, each of the present claims requires that the catheter have a plurality of drug delivery ports that are movable between an open position to deliver the drug to the patient and a closed position. Nothing in either of Heil or Urry teach or suggest this feature of the present claims. In fact, it is submitted that since Heil relies upon the use of plastic film that serves as physical barrier over the ports, the presence of ports that open and close would unnecessary and therefore not obvious to one of skill in the art.

Finally, it is noted that claim 16 has been amended to limit the coating to a material selected from the group consisting of connective tissue growth blocker, C-Proteinase blocker, and prolyl hydroxylase blocker. These materials are neither taught nor suggested by either Heil or Urry. Accordingly, claim 16 is patentable under 35 U.S.C. 103(a) over the combination of Heil and Urry for this additional reason.

## CONCLUSION

Applicants submit that they have shown that claims 13-16 are patentable over the cited references. They request reconsideration of the rejections and allowance of all claims.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

Kagan Binder, PLLC

Dated: August 14, 2008

By: James V. Lilly

James V. Lilly, Reg. No. 27,817
**Customer Number 33072**
Phone: 651-275-9844
Facsimile: 651-351-2954

46610